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February 7, 2013

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Results of repeated dose 90-day oral toxicity studies in Wistar rats with a developmental pesticide, [redacted]

Dear Section 8(e) Coordinator:

[redacted] is submitting results of a Repeated Dose 90-day Oral Toxicity Study in Wistar rats (administered via the diet) with [redacted] conducted by [redacted]. The test substance is a developmental pesticide.

The study was carried out with reference to the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals; Method No. 408: Repeated Dose 90-day Oral Toxicity Study in Rodents; adopted 21 Sep 1998
- Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Part B: Methods for the determination of toxicity and other health effects: B.26. Repeated Dose 90-Day Oral Toxicity Study in Rodents; Official Journal of the European Union, No. L 142.
- U.S. EPA Health Effects Test Guidelines OPPTS 870.3100; Aug 1998
- JMAFF, The guidelines related to the study reports for the registration application of pesticide, No. 12-Nousan-8147, 2-1-9: 90-day repeated dose oral toxicity tests

The test substance was administered via the diet to groups of 10 Wistar rats for up to 90 days. The concentration levels were 100, 500, 1500 and 3000 ppm. During the administration period all animals were examined for clinical signs of toxicity. At the end, all animals were sacrificed and clinical pathology as well as pathology parameters were examined.

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The following is a summary of the most relevant results:

Test group 4 (3000 ppm):

- Significantly reduced mean terminal body weights in males
- Significantly increased absolute and relative liver weights in both sexes
- Significantly increased relative epididymides weights
- Significantly increased relative kidney weights in both sexes
- Significantly increased relative thyroid glands weights in both sexes
- Discoloration in all kidneys in both sexes
- Discoloration in all livers in both sexes
- Liver enlargement in 2 of 10 males and 4 of 10 females
- Epididymides with focus in 5 of 10 animals
- Spermatogenic granuloma in the epididymides in 5 of 10 animals
- Focal cribriform change in the epididymides in 10 of 10 animals
- Increased mitotic figures in the liver in 6 of 10 males
- Multinuclear hepatocytes in 10 of 10 males and 9 of 10 females
- Follicular hyperplasia/hypertrophy of the thyroid gland in 6 of 10 males and 9 of 10 females
- Altered colloid in the thyroid gland in 7 of 10 in both sexes
- Tubular pigment storage in the kidney in 9 of 10 males and all females
- Diffuse fatty change in the adrenal cortex in 9 of 10 males

Test group 3 (1500 ppm):

- Significantly reduced terminal body weights in males
- Significantly increased absolute and relative liver weights in both sexes
- Significantly increased relative kidney weights in both sexes
- Significantly increased relative thyroid glands weights in males
- Discoloration in 6 of 10 kidneys in males and 5 of 10 kidneys in females
- Discoloration in 9 of 10 liver in both sexes
- Epididymides with focus in 1 of 10
- Spermatogenic granuloma in the epididymides in 1 of 10 animal
- Focal cribriform change in the epididymides in 8 of 10 animal
- Multinuclear hepatocytes in 7 of 10 males and 2 of 10 females
- Follicular hyperplasia/hypertrophy of the thyroid gland in 7 of 10 males and 3 of 10 females
- Altered colloid in the thyroid gland in 7 of 10 males and 3 of 10 females
- Tubular pigment storage in the kidney in 5 of 10 both sexes
- Diffuse fatty change in the adrenal cortex in 2 of 10 males

Test group 2 (500 ppm):

- Significantly increased absolute and relative liver weights in both sexes
- Significantly increased relative thyroid glands weights in males
- Multinuclear hepatocytes in 2 of 10 males
- Altered colloid in the thyroid gland in 1 of 10 females
- Tubular pigment storage in the kidney in 1 of 10 females

[redacted] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures